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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Josef Michl

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,239	Applicant(s) MICHL ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 4-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/17/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Claims 1-24 are pending.

Claims 4-24, drawn to non-elected inventions are withdrawn from examination.

Claims 1-3 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

3. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Ma et al./ U.S. Patent number 5,786,221 (issued July 28, 1998) is withdrawn in view of Applicants' arguments presented in the Remarks/Arguments submitted May 26, 2009, page 2 last paragraph.

4. The rejection of claim 2 under 35 U.S.C. 102(e) as being anticipated by Glassy et al./ U.S. Patent Application Publication number U.S. 2002/0098581 A1 (filed December 20, 2001/ IDS reference submitted December 26, 2005) is withdrawn in view of Applicants' arguments presented in the Remarks, page 4, 2nd paragraph.

New Grounds of Objections

Claim Objections

5. Claims 1 and 2 are objected to because of the following informalities: they both cite different means to denote kilodaltons. Claim 1, line 3 cites “kDa”, while claim 2, line 2 cites “kD”. Applicants should select one designation for consistency and clarity. Correction is required.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is

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determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. The rejection of claims 2 and 3 under 35 U.S.C. 102(b) as being anticipated by Ma et al./ U.S. Patent number 5,786,221 (issued July 28, 1998) is maintained.

Applicants assert “Ma... [does] not teach anywhere...the molecular weight range of about 36 to about 38 kD...”, see page 2, last paragraph of Remarks. This argument has been carefully considered, but is not found persuasive.

Applicants submit Ma does disclose antigens within pancreatic extract that includes a 34 kD protein, see page 2 of Remarks, last paragraph. Moreover, Applicants' arguments and specification seem to be remiss of a clear definition of what the term “about” is regarded. It is not clear as to what numbers are regarded as reading on and not reading on “about 43.5 kDa”. Ma discloses a pancreatic antigen which is 34 KD according to SDS-PAGE, see column 6, lines 32-44. This disclosed protein reads on a soluble pancreatic carcinoma antigen 3C4-Ag having a molecular weight of about 36 to about 38 kD and an immunologically active fragment of the antigen recited in claim 1.

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8. The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Hobbs et al. (Oncodevelopmental Biology and Medicine 1: 37-48, 1980), as evidenced by Escribano-Crespo et al./ U.S. Patent number 4,843,019 (issued June 27, 1989) is maintained.

Applicants assert "Hobbs...[does] not anywhere teach the specific molecular weight of about 43.5 kDa or the molecular weight range of about 36 to about 38 kD...", see Remarks, page 3, 3rd paragraph. These assertions have been carefully considered, but are not found persuasive.

Applicants' arguments and specification seem to be remiss of a clear definition of what the term "about" is regarded. It is not clear as to what numbers are regarded as reading on and not reading on "about 43.5 kDa" and "about 36 to 38 kD" and do read on the two recitations. In absence of a definition of "about" and what numbers should be regarded as "cut-off" numbers, the instant rejection is maintained.

Hobbs discloses a pancreatic antigen which is 40 KD and reads on all three examined claims, see column 1, lines 16-33. This antigen is found in foetal pancreas and carcinoma of the pancreas and not in normal pancreas, see Figure 2 caption on page 39 of Hobbs.

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9. The rejection of claims 1 and 3 under 35 U.S.C. 102(e) as being anticipated by Glassy et al./ U.S. Patent Application Publication number U.S. 2002/0098581 A1 (filed December 20, 2001/ IDS reference submitted December 26, 2005) is maintained.

Applicants aver while Glassy does disclose a SK1 antigen having 42-62 kD it is not Applicants' claimed 3C4-Ag antigen or an immunologically active fragment of 3C4-Ag, see page 4 of the Remarks, 2nd paragraph. These points of view have been carefully considered, but found not to persuade.

The proteins disclosed by Glassy read on Applicants' range of a molecular weight of about 43.5 kDa. The properties and functions of the product are not separable, meaning the SK1 antigen of Glassy which is 42-46 kD according to a SDS-PAGE gel reads on Applicants' claims. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), see MPEP 2112.01. The rejection is maintained for the reasons of record.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a *flexible schedule*, however she can normally be reached between the hours of 7:30 am to 6:30 pm, Monday through Saturday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
19 March 2010
/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643